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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,891	03/31/2004	Maurice Arthur Trehella	GRH0105PUSA	7582

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EXAMINER

HA, JULIE

ART UNIT	PAPER NUMBER
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1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/814,891	Applicant(s) TREWHELLA ET AL.	
	Examiner Julie Ha	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment filed on November 13, 2006 is acknowledged. The Applicants elected the claims of Group I (claims 1-33), method for yeast-mediated reduction of an organic compound. After reviewing the Restriction, it was determined that the Restriction was insufficient since it did not contain an Election of species for wherein an agent is a sugar and a list of compounds disclosed. Thus, the previous Restriction has been vacated and a new Restriction follows below. Restriction between the Groups is same except the Restriction now contains further Election of species. Claims 1-34 are pending in this application.

Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-33, drawn to a method for yeast-mediated reduction of an organic compound, classified in class 435, subclass 128.
 - II. Claim 34, drawn to organic compounds, classified in class 568, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case organic compounds can be reduced by chemical reactions.

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4. The several inventions listed above are independent and distinct from one another as they have acquired a separate status in the art and required independent searches, particularly with regard to the literature searches. Clearly, a reference which would anticipate one of the above groups would not necessarily anticipate or even make obvious the other groups.
5. An undue burden would ensue from the examination of a product having multiple methods of preparation. Burden lies not only in the search of the US Patents, but in the search for literature and foreign patents and examination of claim language and the specification for compliance with the statutes concerning new matter, distinctness and scope of enablement.
6. Therefore, because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election

7. This application contains claims directed to the following patentably distinct species:

If Group I is elected, Applicants are requested to elect a single disclosed species as below.

- I. Applicants are requested to elect one of the following organic compound species:

A. ketone;

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- B. alkenes;
- C. alkynes;
- D. aldehydes;
- E. imines;
- F. hydroxamines;
- G. β -keto amides;
- H. β -keto esters;
- I. enol ethers;
- J. activated ketones;
- K. conjugated alkenes;
- L. Formula I;
- M. Formula II;
- N. Formula III;
- O. Formula IV.

The species are independent and distinct because these organic compounds have different structures and different variables. Further, search for enol ethers would not necessarily lead to aldehydes since they have distinct structures.

If Formulas I-IV are elected as species, then the Applicants are further requested to elect single disclosed variables for all variables associated with that formula. For example, if Formula I is elected, then R_1 - R_4 need to be specified. That is, Applicants need to specify what aryl group R_1 is and whether it is substituted or unsubstituted, what

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substituted C₁-C₆ alkyl group R₂ and R₃ are, and what R₄ variable is, and so on. If

Formula IV is elected, then a single disclosed variables for R₈-R₁₁ must be specified.

II. Applicants are requested to elect one of the following precursor compounds from claim 23:

- A. fluoxetine;
- B. tomoxetine;
- C. duloxetine;
- D. nisoxetine;
- E. epinephrine;
- F. norepinephrine;
- G. ethylnorepinephrine;
- H. isoproterenol;
- I. isoetharine;
- J. metaproterenol;
- K. terbutaline;
- L. metaproterenol;
- M. phenyleprine;
- N. ritodrine;
- O. prenalterol;
- P. methoxamine;
- Q. albuterol or derivative thereof;
- R. salmeterol;

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S. ephedrine;

T. pheynylpropanolamine.

The species are independent and distinct because these organic compounds have different structures and different variables. Further, search for epinephrine would not necessarily lead to albuterol since they have distinct structures.

III. Applicants are requested to elect one of the following compound of

Formula IV precursors:

A. fluoxetine;

B. tomoxetine;

C. duloxetine;

D. nisoxetine;

E. epinephrine;

F. norepinephrine;

G. ethylnorepinephrine;

H. isoproterenol;

I. isoetharine;

J. metaproterenol;

K. terbutaline;

L. metaproterenol;

M. phenyleprine;

N. ritodrine;

O. prenalterol;

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- P. methoxamine;
- Q. albuterol or derivative thereof;
- R. salmeterol;
- S. ephedrine;
- T. pheynylpropanolamine;
- U. amphetamine or a derivative thereof;
- V. hydroxyamphetamine;
- W. methamphetamine;
- X. benzphetamine;
- Z. fenfluramine;
- aa. propylhexedrine;
- bb. ibuprofen;
- cc. naproxen;
- dd. alminoprofen;
- ee. fenoprofen;
- gg. flurbiprofen;
- hh. indoprofen;
- ii. ketoprofen;
- jj. suprofen.

The species are independent and distinct because these organic compounds have different structures and different variables. Further, search for epinephrine would not necessarily lead to ibuprofen since they have distinct structures.

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IV. Applicants are requested to elect one of the following pharmaceutical compound:

- A. sympathomimetic amine;
- B. an ethyl amine;
- C. propylamine;
- D. propionic acid
- E. an arylethylamine;
- F. an arylpropylamine;
- G. a propionic acid with a 2-aryl substitution.

The species are independent and distinct because these pharmaceutical compounds have different structures and different functions. Further, sympathomimetic amines mimic the effects of the hormones adrenaline and noradrenaline, while propionic acid is naturally occurring carboxylic acid with chemical formula $\text{CH}_3\text{CH}_2\text{COOH}$ and is used to inhibit the mold and bacterial growth.

8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 3, 7-8, 12, 14-33 are generic.

9. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

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10. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

11. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

13. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

14. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

15. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusions

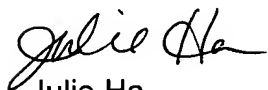
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982.

The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Julie Ha
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